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IN THE SUPREME COURT OF THE UNITED STATES

LABORATORY CORP. OF AMERICA HOLDINGS,

Petitioner,

v.

METABOLITE LABORATORIES, INC., *et al.*,

Respondents.

On Writ of Certiorari To The United States Court of Appeals For the Federal Circuit

BRIEF *AMICUS CURIAE* OF AARP IN SUPPORT OF PETITIONER

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STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

AARP is a nonpartisan, nonprofit membership organization of more than 35 million people, age 50 or older, dedicated to addressing the needs and interests of older Americans. AARP works to foster the health and economic security of individuals as they age, and to ensure access to high quality and economical health care. Older people are susceptible to vascular disease, cognitive dysfunction, and cancer, diseases associated with elevated homocysteine levels in the body.

Patents that claim the mental process of recognizing a medical phenomenon of nature leally prohibit diagnosis and treatment, and discourage communication of medical information. In light of the significance of the issues presented in this case, AARP respectfully submits this brief *amicus curiae* urging the Court to find that such patents are invalid and to clarify the limits of indirect liability.

SUMMARY OF ARGUMENT

The patent in this case improperly claims the mental process of recognizing a phenomenon of nature. The lower courts held a diagnostic test provider indirectly liable for inducing infringement based on physicians ordering and reviewing the results of an unpatented diagnostic test and then

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[1] In compliance with Rule 37.6 of this Court, *amicus curiae* AARP states that no counsel for any party authored this brief in whole or in part, and that no party or entity other than this *amicus curiae*, its members or its counsel made a monetary contribution to the preparation or submission of this brief. Counsel for AARP gratefully acknowledge the assistance of Glushko-Samuelson Intellectual Property Law Clinic students Gabriel Groisman and Cynthia Lan. Written consent of the parties has been obtained and will be filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

recognizing the probability that a patient has a medical condition. Direct infringement should not result for physicians who cannot avoid mentally recognizing the correlation when they order the unpatented test for previously known uses. Nor should indirect liability be based on the acts of communicating knowledge of this medical phenomena or of communicating knowledge of or performing a previously known and unpatented test. The lower courts' injunction also improperly removed the test from the public domain.

This patent and others like it threaten public health by preventing patients and physicians from performing and providing needed diagnostic procedures and treatments. Such patents, and the indirect liability that may be associated with them, discourage patients, physicians, and others from communicating medical knowledge, and thus from discovering the need for medical diagnosis and treatment.

Patents have never been allowed to claim laws of nature, natural phenomena, or mental processes because scientific knowledge is not subject to proprietary ownership. Nor do such basic mental processes become patentable by adding insignificant physical steps. The claim at issue here is thus invalid, and Congress never authorized it.

ARGUMENT

I. A Diagnostic Test Provider Was Held Indirectly Liable Based on Physicians Recognizing the Probability that a Patient Has a Medical Condition.

This case involves a patent that claims the mental process of recognizing a phenomenon of nature, *i.e.*, the statistical correlation between elevated levels of homocysteine (an amino acid) in blood or urine and the condition of having

a vitamin B deficiency. U.S. Patent No. 4,940,658, Claim 13, issued July 10, 1990 ("'658 patent"). Through overly broad construction of the patent claim and the evidence, the lower courts found that physicians directly infringed the patent by thinking about this relationship whenever they ordered or reviewed unpatented total homocysteine tests that had been previously used to diagnose and treat diseases. Through expansive interpretation of the law of indirect liability, the lower courts may have found a diagnostic company liable merely for communicating the existence of this statistical correlation to physicians and for encouraging and subsequently performing the unpatented diagnostic tests. The lower courts, moreover, enjoined any and all use of the unpatented diagnostic tests. Currently, the diagnostic company cannot perform these unpatented tests and physicians and patients cannot use them without a license to diagnose or treat known diseases.[2] Through these holdings, the lower courts have impermissibly withdrawn the unpatented diagnostic tests and their previously known uses from the public domain. *See Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966) ("Congress may not authorize . . . patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.")

A. The Purported Invention Is the Mental Process of Recognizing a Statistical Correlation Between a Measurement and a Medical Condition.

The '658 patent summarizes the "invention" as the

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[2] The patentee has chosen to expressly or impliedly license Claim 13 when licensing its patented homocysteine tests. Otherwise, no one could legally perform the diagnostic test.

> discover[y] that an elevated level of total homocysteine in tissues of warm blooded animals correlates both with cobalamin deficiency and with folic acid deficiency; an animal with elevated levels of total homocysteine is likely to have one or both deficiencies, but the assay does not distinguish between the two.

'658 Patent at col. 4, lines 17-23 (emphasis added).[3] The text of the claim at issue, Claim 13, reads in its entirety:

> 13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of: assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of homocysteine in said body fluid with a deficiency of cobalamin or folate.

Id. (emphasis added). Claim 13 is not limited to any particular method of or equipment for assaying or correlating.

The term "assay" is defined as "1. Test of purity; trial. 2. To examine; to subject to analysis. 3. The quantitative or qualitative evaluation of a substance for impurities, toxicity, etc.; the results of such an evaluation." *Stedman's Concise Medical Dictionary for the Health Professions* 81 (4th ed. 2001). The '658 Patent explains that "assaying" involves the physical step of "quantifying sulfhydryl amino acid concentrations in a sample," which for Claim 13 means

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[3] Separately claimed methods of measuring total homocysteine are not at issue. This discovery may not have been new. *See, e.g.*, Gloria Bucco, *Dialog with the Experts: Kilmer McCully, M.D., Connects Homocysteine and Heart Disease*, Nutrition Science News (July 1999) available at www.newhope.com/nutritionsciencenews/NSN_backs/jul_99/dialogue.cfm (last visited Dec. 21, 2005).

"quantifying total homocysteine concentrations in samples of body tissue from a warm-blooded animal." '658 Patent at col. 1, lines 9-13.

The '658 patent itself recognizes that "several different [previously] known assays suitable for use in determining levels of total homocysteine in urine or blood" already exist, but asserts that their use "to detect cobalamin or folic acid deficiency" was not previously known. '658 Patent at col. 6, lines 6-9.[4] The patent and the medical literature recognize that many previously known uses of total homocysteine assays in diagnosing and treating diseases exist, such as diagnosing heart disease and monitoring drug treatments for homocystinuria. *See* '658 Patent at col. 6, lines 14-16 and 33-39; Helga Refsum, Sveln Helland & Per M. Ueland, *Radioenzymatic Determination of Homocysteine in Plasma and Urine*, 31 Clinical Chem. 624, 624 (1985).

The patent does not define "correlating" or an "elevated level," although it does recite "normal" ranges of blood and urine total homocysteine values in humans and states that "levels above these ranges are indicative of cobalamin and/or folate deficiency; the higher the level, the stronger the indication." '658 Patent at col. 9, lines 23-29. To "correlate" is "1. To put or bring into causal, complimentary, parallel, or reciprocal relation. 2. To establish or demonstrate as having a correlation." *The American Heritage Dictionary of the English Language* 299 (1981). The claim by its own terms thus does not require a determination that any individual whose blood or urine was assayed in fact has a cobalamin or folate

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[4] Although the assaying equipment used in this case was developed after the patent, and is itself unpatented, Claim 13 applies to any unpatented total homocysteine assay. *See, e.g.*, Petition for Writ of Certiorari, *Laboratory Corp. of America Holdings v. Metabolite Labs., Inc.*, No. 04-607, at 4-6.

deficiency.[5] *See* District Court Order of Nov. 29, 2000, at 2, JA 59 (the invention as a whole claims the mental process of "'determining the existence of'" a deficiency ... although not necessarily "with 100% accuracy.") *Cf. Metabolite Labs., Inc. v. Laboratory Corp. of America Holdings*, 370 F.3d 1354, 1364 (Fed. Cir. 2004) ("the claim language does not require a confirmatory step linking these conditions to diagnosed or apparent symptoms.")

The correlating step is to be performed (according to one of the inventors) by mental recognition of the existence of the statistical association.

> The physician takes the value that's been determined by the assay and then based on everything the physician knows about the patient, he or she establishes a mutual relationship between an elevated value ... if the physician thinks the value is elevated for an individual patient and a deficiency of cobalamin or folate, or if the physician believes that for a particular patient the value is not elevated, then that physician in their mind establishes that there is not a deficiency of cobalamin or folate.

Trial Tr. at 980-81, JA 140-41. *See id.* at 507, 981, JA 111, JA 141 (correlating is "all done in the mind.") Claim 13 thus seeks to patent the mental process of recognizing a phenomenon of

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[5] The claim does not require that the "elevated level" is to be determined with reference to a normal value specific to the particular animal whose blood or urine was assayed. *See* Trial Tr. at 493, JA 109. Further, the correlating step does not require use of a previously measured "elevated level" when determining that a correlation exists between an elevated level and and a deficiency for that type of body fluid. Rather, the claim uses the indefinite article "an" in the correlating step, suggesting that a different "elevated level" is to be employed.

nature, *i.e.*, the statistical risk of a vitamin deficiency for any particular homocysteine concentration in body fluid, once the fluid has been assayed for its total homocysteine content.

B. Physicians Were Found To Directly Infringe By Ordering or Reviewing Unpatented Assays and Then Recognizing The Statistical Correlation.

The District Court granted summary judgment that Laboratory Corporation of America Holdings ("LabCorp") did not directly infringe the patent. LabCorp did not perform the '658 patent's correlating step, even though LabCorp performed the assays and knew of elevated levels and of the correlation between those levels and vitamin deficiency. At trial, the jury found LabCorp liable for indirect infringement. 370 F.3d at 1354. The jury found that LabCorp induced direct infringement under 35 U.S.C. § 271(b) and contributed to infringement under 35 U.S.C. § 271(c).[6] The Court of Appeals affirmed the holding of inducing infringement but declined to address the contributory infringement issue. The necessary prerequisite for such indirect infringement liability is the direct infringement by another. *See, e.g., Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 774 (Fed. Cir. 1993). Thus, the jury impliedly found that physicians directly infringed by performing the patented process.

However, there was no direct evidence at trial that any physician performed both the step of assaying homocysteine levels and the step of correlating the results with a vitamin deficiency. There was no evidence that any physician measured

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[6] LabCorp contested the sufficiency of the evidence as to these holdings. *See* Corrected Brief for Appellant Laboratory Corporation of America Holdings, *Metabolite Labs.*, at 23-36 (Fed. Cir.) ("LabCorp App. Brief").

homocysteine levels themselves. *See Metabolite Labs.*, 370 F.3d at 1364 n.1 (not reaching the meaning of or evidence for the assaying step). The finding thus must have been premised on interpreting the assaying step to require only ordering or receiving the results of assays, or on treating LabCorp as the physicians' agents. *See, e.g., Cross Medical Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1311 (Fed. Cir. 2005) (direct liability requires the defendant or its agents to perform all steps of the process). If direct liability was based only on ordering or reviewing the test, then this interpretation of the claim contradicts the meaning of "assaying" described in the patent's specification.

Nor was there direct evidence that any physician performed the "correlating" step. The Court of Appeals upheld the implicit finding of direct infringement on the basis of circumstantial evidence that physicians had performed the correlating step. 370 F.3d at 1364-65. The District Court construed that step to require only mentally determining an "elevated" level of homocysteine — *i.e*, a level "above the normal range" for the relevant type of animal's body fluid — and "establish[ing] a mutual or reciprocal relationship between" the elevated level and a deficiency of cobalamin or folate. District Court Order of Nov. 29, 2000, at 2-3, JA 59-60. Under this construction, the jury could have found that physicians directly infringed simply by thinking about the statistical correlation for any particular elevated value in response to reading LabCorp's (or anyone else's) medical publication, so long as some total homocysteine assays had previously been ordered or received by physicians. In fact, the jury could have found that physicans directly infringed by ordering the assays and using them for an entirely different and long-standing medical purpose, so long as they incidentally thought about the statistical correlation of any measured value to cobalamin or folate deficiency.

Significantly, the jury verdict on damages assumes that all of the physicians ordered unpatented assays to determine a deficiency or unavoidably performed the correlation when using the assay for other purposes. LabCorp challenged the award for lack of evidence that every physician who received assay results performed the correlation, as there was no evidence that all physicians knew of the correlation or intended to perform it. *See* Memorandum in Support of Laboratory Corporation of America Holding's Renewed Motion for Judgment as a Matter of Law ("JMOL Motion") at 6-8. *Cf. Metabolite Labs.*, 370 F.3d at 1364 (citing testimony that "it would be malpractice for a physician to receive a total homocysteine assay without determining cobalamin/folate deficiency.") If sustained, the award would indicate that the patent itself would convert physicians' long-practiced medical procedures into unavoidable infringements, based on physicians' inevitable mental recognition of the statistical correlation that the patent itself disclosed. The patent thus would impermissibly withdraw previously known medical technology and medical knowledge from the public domain. *See Graham*, at 6.

But even if Claim 13 were restricted to intentionally performing the correlation in regard to actual values for patients obtained from assays performed by physicians, the patent would prohibit physicians from practicing good medicine without a patent license. Congress has previously precluded patent claims and remedies against physicians and related health care entities that perform or induce the "performance of a medical activity." 35 U.S.C. § 287(c)(1). The physician exception does not apply in this case, because it is only applicable to patents filed after Sept. 30, 1996, whereas this patent was filed Nov. 20, 1986. 35 U.S.C. § 287(c)(4). Although physicians were not sued here, physicians performing a process claimed by a patent filed after 1996 would not be

clearly immunized from patent infringement liability. The statute defines "medical activity" as "performance of a medical or surgical procedure on a body." 35 U.S.C. § 287(c)(2)(A). Although taking blood may constitute such a procedure, requesting a patient to provide a urine sample, ordering an assay for the sample, and reviewing and correlating the assay results all may not. And even if physicians are themselves immune from claims and remedies, their conduct can still constitute direct infringement that may form the basis for the liability of patients and of others who encourage or assist the practice of medicine, like LabCorp in this case.

C. Indirect Infringement Should Not Be Proven By Evidence of Communicating the Patent's Own Medical Disclosure or of Performing Unpatented Assays.

The jury was instructed that to find inducement liability LabCorp must have "actively and knowingly aided and abetted that direct infringement ... [and] knew or should have known that its actions would induce actual infringement." Trial Tr. at 1829. *Compare Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990) (actual intent to induce the act that constitutes direct infringement is required) *with Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990) (constructive or actual knowledge required that the induced act constitutes a direct infringement). The jury was also told, however, that it could find inducement if LabCorp "provided instructions and directions to perform the infringing act through labels, advertising and other sales methods" or "by supplying the components that are used in an infringing method or apparatus with the knowledge and intent that its customers would directly infringe by using the components to make, use, or sell the patented invention." Trial Tr. at 1830 (emphasis added). Such instructions were improper

where the patent claims a new method of recognizing a natural phenomenon using previously known measuring equipment.

These improper instructions may have resulted in LabCorp being found to have induced infringement without the requisite conduct or intent. The unpatented assays purchased and performed by LabCorp and knowledge of their other uses were already in the public domain. Thus, to find liability, the jury could have based its inducement verdict on impermissible grounds, either on the act of communicating what the patent itself disclosed or on the act of communicating the assays' results.[7] *See Metabolite Labs.*, 370 F.3d at 1365 (stating that a reasonable jury could find inducement merely from publishing information that "advocate[s] use of the assay to identify a need for cobalamin/folate supplements."). Alternatively, and just as improperly, the jury could have found indirect infringement based solely or primarily on the service of performing the unpatented assays for previously known uses with knowledge that correlation to a cobalamin or folate deficiency might be performed. *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003) ("where a product has substantial noninfringing uses, intent to induce infringement cannot be inferred even when the defendant has actual knowledge that some users of its product may be infringing the patent.")

There were three categories of evidence purporting to establish that LabCorp aided and abetted infringing activity with requisite intent to induce infringement. These were: medical publications and advertisements that recited the

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[7] Either of these bases raises serious First Amendment concerns. *See, e.g., Washington Legal Foundation v. Henney*, 202 F.3d 331, 332-36 (D.C. Cir. 2000) (noting First Amendment concerns raised by regulatory guidelines that prohibited dissemination of certain "off-label" medical information).

existence of the correlation between homocysteine and cobalamin or folate deficiency (which inherently provided a reason for physicians to order assays and to perform the correlation); medical publications and advertisements that recited the existence of the unpatented assays and various unpatented uses of the assay results (which inherently provided a reason for physicians to order assays that might also be used to perform the correlation by physicians who know of it); and actually performing the unpatented assays (which inherently provided assistance to physicians who might perform the correlation if they knew of it). If such evidence is itself sufficient to prove inducement, it will extend liability to an absurd extent and will threaten public health even more seriously than just preventing the particular diagnostic test from being performed.[8] Nor should such evidence result in contributory infringement liability.

1. Disseminating Medical Information In the Patent's Own Disclosure Or The Prior Art Should Not Be Grounds For Virtually Unlimited Inducement Liability.

Medical publications and advertisements that merely disclose a newly discovered correlation do not aid and abet infringement any more than does publication of the patent's disclosure itself. Broad dissemination of the information contained in a patent is the central premise of granting patent

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[8] Because such evidence inherently encourages proper medical treatment, it should be considered irrelevant to inducing infringing conduct with improper intent and should be excluded under Fed. R. Evid. 401. Because juries are likely to give improper weight when considering other evidence of acts and intent to encourage infringement, it should also be deemed unduly prejudicial under Fed. R. Evid. 403.

rights.[9] Moreover, when a patent discloses and claims the mental process of recognizing a medical phenomenon, broad dissemination of the patent's disclosure is necessary to promote public health and should be a primary public policy.

However, the decision below not only serves to thwart the exchange of knowledge, it fails to establish any reasonable limitation on liability for dissemination of the information. For example, nothing in the jury instructions or in the Court of Appeals' reasoning required LabCorp to profit from the encouragement to perform the patented process provided by its medical publications or advertisements, and nothing in the law of inducement liability imposes such a requirement.[10] Thus, the inducement standard applied below would improperly extend liability to all people who seek to disseminate medical (and other scientific) information disclosed by such a patent, even though they lack any connection to the direct infringer and any pecuniary interest in the patented process.

Further, nothing in the jury instructions or in the Court of Appeals' reasoning limited evidence of inducement to publications or advertisements that specifically aided and abetted (and reflected an intent to encourage) the unauthorized

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[9] *See, e.g., Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989) (" patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right.") *See generally* Malla Pollack, *What is Congress Supposed to Promote?: Defining "Progress" in Article I, § 8, Clause 8 of the United States Constitution, or Introducing the Progress Clause*, 80 Neb. L. Rev. 754 (2001).

[10] In contrast, such profit is the hallmark of vicarious liability. *See Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 125 S.Ct. 2764, 2767 (2005) (one "infringes vicariously by profiting from direct infringement while declining to exercise a right to stop or limit it.").

performance of a patented process. Inducement liability does not and should not extend to assisting and encouraging use of the patented process with indifference to whether third parties will infringe (even knowing that some may).[11] The alternative would prevent dissemination of the medical knowledge disclosed by patents, and would prevent physicians from recommending medical procedures to their patients.

Similarly, medical publications and advertisements disclosing existing uses for and offering to perform unpatented diagnostic technologies should not be the basis for inducement liability. To do so would permit the grant of a patent to prohibit public discussion of technology already within the public domain. *See Graham*, 383 U.S. at 6.

2. Performing Unpatented Medical Procedures Should Not Be Grounds For Virtually Unlimited Inducement Liability.

Actually performing unpatented and previously known medical procedures also should not be the basis for inducement liability, even knowing that the results may be used to infringe a patented process. To do so would impermissibly withdraw those procedures and their results from the public domain.

Even if this outcome were permissible, it would be impractical. To avoid such liability, companies or individuals that perform the assaying step would have to police the

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[11] *See Metro-Goldwyn-Mayer Studios*, 125 S.Ct. at 2779; *id.* at 2782 n.13. Particularly in regard to patents such as the one at issue, the Court should narrow its overly broad dicta in *Metro-Goldwyn-Mayer Studios* that "active steps ... such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe." 125 S.Ct. at 2779 (emphasis added). *See Warner-Lambert Co.*, 316 F.3d at 1365.

thoughts of patients and physicians who would receive the assay results. Simply warning patients and physicians not to perform the correlation without a license may not suffice to avoid inducement liability.

3. Performing Unpatented Medical Procedures Should Not Be Grounds For Virtually Unlimited Contributory Liability.

The jury verdict that LabCorp contributed to infringement also raises serious concerns about the scope of potential liability.[12] The verdict was challenged below because there were substantial non-infringing uses of the unpatented assays and because the assays were not especially adapted for infringing uses. *See, e.g.*, JMOL Motion at 8-10; LabCorp App. Brief at 31-34. Because the Federal Circuit did not address the issue, the contributory liability verdict still stands.

The provision against contributory patent infringement, 35 U.S. C. § 271(c), however, prohibits only selling or offering to sell "a material or apparatus for use in practicing a patented process...." Although Abbott Laboratories might be found to contribute to infringement by selling total homocysteine assaying equipment, LabCorp sold only the service of assaying, which is neither a "material" nor an "apparatus." Further, total homocysteine assays and their uses to diagnose and treat various disease conditions were admittedly part of the prior art. Thus, the verdict must be premised on the patent's own disclosure having eliminated all of the prior art assays' "substantial non-infringing use[s]" and having rendered all

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[12] Physicians and related medical companies that perform such unpatented assays for other physicians or for patients clearly are not immunized from contributory infringement liability, because § 287(c)(1) does not reference § 271(c).

such assays "especially adapted for use in an infringement." 35 U.S.C. § 271(c). Therefore, the contributory liability holding also impermissibly withdraws the unpatented assays and their prior art uses from the public domain.

D. The Injunction Impermissibly Prohibits All Previously Known Uses of Unpatented Assays and Immediately Threatens Public Health.

As a result of the inducement and contributory liability verdicts, the lower courts enjoined performance of all prior art uses of the unpatented prior art total homocysteine assays. *See* 370 F.3d at 1371-72 (prohibiting "any homocysteine-only test.") Not only does this injunction impermissibly withdraw those assays and their previously known uses from the public domain, it immediately threatens the public health of countless patients who otherwise might learn if they suffer from various diseases or who may need to use those assays as part of their medical regimen. *See Graham*, 383 U.S. at 6.

It is impossible to imagine an injunction for such a patent that would not be overly broad. Once the statistical correlation has become common knowledge, physicians have multiple reasons to order the prior art assays. An injunction prohibiting assaying only where the primary or sole purpose is to determine cobalamin or folate deficiency would be unworkable. An injunction prohibiting assaying only for physicians who know of the correlation also would be unworkable. Even if so limited, the injunction would threaten public health by requiring a license to diagnose and treat a known medical condition based on the newly discovered natural correlation to the prior art assay results.

II. Patents for Mental Processes of Recognizing Natural Phenomena Threaten Public Health and Interfere With the Practice of Medicine.

This patent, and any other patent that would claim the mental process of recognizing natural phenomena, threatens public health and interferes with the practice of medicine. The patent prevents the practice of existing medical procedures using previously known and unpatented medical technology and knowledge, and taxes the use of such technology to obtain the benefits of a new medical discovery. Furthermore, the threat of indirect liability associated with the patent discourages communication regarding the medical discovery and the need to perform diagnostic and treatment procedures. As a result, the practice of medicine suffers.

A. Patients Who Might Directly Infringe May Forego Diagnosis and Treatment.

Like the physicians discussed above, patients who learn of the correlation between total homocysteine and vitamin deficiency are unable to avoid practicing the patented process if they order or obtain the results of total homocysteine assays. Unlike physicians, patients are not immune from direct infringement for their own activities. Nor do patients enjoy immunity if they induce infringement by physicians. In addition, physicians may act as the agents of their patients when they unilaterally or at their patients' request perform the patented process. Patients thus may be held directly liable based on the acts of their physicians, notwithstanding § 287(c).

Patients and physicians can no longer reasonably assume that they will not be sued for infringement. *Cf.* Recording Industry Association of America, *Frequently Asked*

Questions About The Recording Industry's Use of John Doe Lawsuits, at http://www.riaa.com/news/newsletter/012104_faq.asp (last visited Dec. 14, 2005) (discussing hundreds of law suits filed against individuals for alleged copyright infringement). Rather than face potential liability, patients and physicians may instead avoid requesting unpatented total homocysteine assays. As a result, patients not only will fail to discover vitamin deficiencies, but they will fail to learn important information that they previously and routinely would have obtained from assays, such as diagnostic indications of heart disease and treatment information for known conditions.

If Claim 13 is upheld, moreover, additional patents will ensue that claim correlations of measured conditions to the risk of diseases. Such patents will force patients and physicians to obtain licenses in order to legally learn how new medical discoveries apply to their particular cases. Such licenses impose a tax on practicing the medical discovery, burdening the delivery and raising the costs of medical services. As these costs rise, public health is diminished.

Additional patents claiming the mental process of recognizing natural medical phenomena are particularly likely to threaten public health if the initial assays can be performed using simple diagnostic tests. *See, e.g., National Survey: Consumer Enthusiasm for Home Diagnostic Tests; Advanced Care (TM) Cholesterol Test Creates New Category in $1 Billion Market*, PR Newswire, June 29, 1994 ("6 out of 10 American households have used a home medical test.") For example, a new discovery that pregnancy is statistically correlated with a risk of a disease might lead to a patent claiming use of home pregnancy tests to diagnose the likelihood of the disease. Assessing pregnancy with knowledge of the correlation would result in direct liability under the lower courts' logic in this case, and the grant of the patent and

dissemination of its teaching would convert such non-infringing pregnancy assessments into unavoidable infringements. As a result, patients could be directly liable for patent infringement when using the test merely by thinking about what the results mean for their health – an absurd result not consistent with the development of rational patent or public health policy, and likely to discourage home or office medical testing rather than promote it.

B. Patients, Physicians, and Others Who Might Indirectly Infringe Will Stop Communicating About the Need for Diagnosis and Treatment.

Patients, physicians, and others may be found to induce infringement under the excessively broad standards applied below simply for disseminating information about the existence of the correlation or the availability of unpatented assays. Like LabCorp, patients who encourage physicians to order or to obtain the results of total homocysteine assays could be held liable for inducing infringement. Physicians (who benefit economically from performing medical procedures) may be held liable for inducing infringement by performing assays or offering to do so, and by informing their patients of the existence of the correlation.

To avoid liability, patients may not inform their family, friends, or physicians of the newly discovered medical phenomena or of the consequent need for diagnosis and treatment. Patients also may not help others to purchase diagnostic equipment or to perform any of the unpatented steps of the patented process. Similarly, physicians may not inform their patients, their colleagues, or the public at large of critical medical information.

As a result of potential inducement liability, medical and scientific journal publishers, the news media, medical and scientific membership organizations, diagnostic equipment and medical treatment suppliers, etc., may refuse to disseminate information about new medical discoveries that are the basis for patented processes. Patients and physicians currently rely on each other and on these third parties to learn of new medical discoveries. *See, e.g.*, K. K. Grandage, et al., *When less is more: a practical approach to searching for evidence-based answers,* 90 J. Med. Lib. Assoc. 298 (2002); J.A. Oheroff, et al., *Physicians' information needs: analysis of questions posed during clinical teaching,* 114 Annals of Internal Med. 576 (1991). Even if patients and physicians learned of new options for diagnosis and treatment from the patents themselves, they may be unable to obtain needed diagnostic and treatment supplies or services, because such suppliers may face indirect liability for patent infringement.

The result of these constraints on communication and medical services will predictably be a dramatic decrease in the level of public awareness and in the quality of medical care. The patent system was never intended to retard medical and scientific progress in this manner.

III. The Court Should Invalidate Claim 13 Because It Improperly Claims a Mental Process of Recognizing a Phenomenon of Nature.

This Court has consistently recognized that not all processes are patentable. Scientific knowledge -- including laws of nature, natural phenomena, and mental processes -- is free from proprietary ownership. Furthermore, patents may not be obtained on scientific knowledge or mental processes merely by adding insignificant prior or subsequent physical steps. In the present case, as the patent seeks to privatize the mental

process of recognizing a natural medical phenomenon, this Court should invalidate the patent. Adding a prior measurement step does not transform this unpatentable claim into a patentable invention.

A. Phenomena of Nature and Mental Processes Are Not Patentable.

The rationale for excluding from patentability laws of nature, natural phenomena, and mental processes rests on the "fundamental understanding that they are not the kind of 'discoveries' that the [patent] statute was enacted to protect." *Parker v. Flook*, 437 U.S. 584, 593 (1978). *See Diamond v. Diehr*, 450 U.S. 175, 185 (1981) (excluding "laws of nature, natural phenomena, and abstract ideas"); *id.* at 195 (Stevens, J., dissenting) (mental steps were unpatentable "on the familiar principle that a scientific concept or a mere idea cannot be the subject of a valid patent"). These categorical exclusions are soundly based on the idea that "[p]henomena of nature ... mental processes and abstract intellectual concepts are ... the basic tools of scientific and technological work." *Gottschalk v. Benson*, 409 U.S. 63, 68 (1972) (emphasis added). *See Funk Bros. Seed Co. v. Kalo*, 333 U.S. 127, 130 (1948) ("manifestations of laws of nature [are] free to all men and reserved exclusively to none"); *Flook*, 437 U.S. at 593 n.15 (patentable inventions must not be "merely heretofore unknown," to avoid depriving the public of prior uses). *Cf.* Dan L. Burk & Mark A. Lemley, *Inherency*, 47 Wm. & Mary L. Rev. 371, 383 (2005) (where the public already has the benefit of the invention, the value of providing knowledge of why the invention works does not warrant its withdrawal from the public domain).

These exclusions derive from the historic understanding that nature and science are the common heritage of mankind, free from appropriation by particular persons.[13]

> If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea.... That ideas should freely spread from one to another over the globe, for the moral and mutual instruction of man, and improvement of his condition, seems to have been peculiarly and benevolently designed by nature, when she made them, like fire, expansible over all space, without lessening their density in any point....

Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), in 13 *The Writings of Thomas Jefferson* 326, 333-34 (Albert Ellery Bergh ed. 1908).

This distinction of nature and science (which could not be made the subject of patents) and technological applications of natural phenomena and scientific principles (which could) was reflected in the Constitution itself. *See* U.S. Const., Art. I, Sec. 8, Cl. 8 ("To promote the Progress ... of useful Arts").[14]

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[13] *See, e.g.*, John Temple Swing, *Who Will Own the Oceans?*, 54 Foreign Aff. 527, 528 (1976) (Dutch jurist Hugo "Grotius's philosophy of 'freedom of the seas' also involved the concept of common ownership, *res communis*, an idea akin in principle to [Arvid] Pardo's 'common heritage,' enunciated three and one-half centuries later.")

[14] *See* Edward C. Walterscheid, *"Within the Limits of the Constitutional Grant": Constitutional Limitations on the Patent Power*, 9 J. Intell. Prop. L. 291, 349 (2002) ("In other words, natural phenomena, laws of nature, or abstract ideas, without more, are not considered to be 'useful arts.'"); Walterscheid, *The Preambular Argument: The Dubious Premise of Eldred v. Ashcroft*, 44 IDEA 331, 343 (2004); Noah Webster, *American Dictionary*

This Court should reaffirm that natural phenomena and scientific knowledge have not yet been withdrawn from the public domain and remain free for all to use.

Moreover, laws of nature, natural phenomena, and mental processes are unpatentable because claims to broadly applicable scientific knowledge would exceed actual inventive contributions and subsequently hinder rather than promote technological progress. *See, e.g., Le Roy v. Tatham,* 55 U.S. (14 How.) 156, 175 (1853) (patent may not claim an "effect" or "the result of a certain process" because it would prohibit other inventions that perform the same functions and discourage technological progress); *Corning v. Burden,* 56 U.S. (15 How.) 252, 268 (1853) (processes not limited to the "method or mode of producing" the desired function are unpatentable). As the seminal case of *O'Reilly v. Morse*, 56 U.S. (15 How.) 62 (1854) holds, one cannot claim all uses of a natural phenomenon for a particular purpose.

> It can hardly be supposed that under such a patent he could have prevented the use of the improved machinery which science has since introduced; although the motive power is steam, and the result is the propulsion of vessels. Neither could the man who first discovered that steam might, by a proper arrangement of machinery, be used as a motive power to grind corn or spin cotton, claim the right to the exclusive use of steam as a motive power for the purpose of producing such effects.

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of the English Language, unnumbered page headed "ARR-ARS-ART" (1st ed. 1828, reprinted in Foundation for American Christian Education (10th ed. 1998)) (defining art).

Id. at 113. *See Diehr*, 450 U.S. at 191 (unpatentability "cannot be circumvented" by limiting "use of the [mathematical] formula to a particular technological environment.")

Although the Court later allowed broad functional claims to processes that apply natural phenomena, it has neither invalidated the core holding of *O'Reilly* nor withdrawn scientific information from the public domain.[15] There remains a critical line to be drawn between unpatentable scientific principles that must remain in the public domain and the patentable applications of those principles. Likewise, the courts must distinguish between overly broad process claims that unduly burden technological progress and narrower process claims that promote it.

B. Insignificant Physical Steps Cannot Transform Unpatentable Scientific Principles or Their Recognition Into Patentable Processes.

This Court has recognized that minor physical steps cannot transform unpatentable scientific knowledge into a patentable invention. In *Flook*, the Court rejected the argument that a method including a mathematical algorithm was patentable because the information output was subsequently used to practical effect. 437 U.S. at 590. The Court reasoned:

> the notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance. A competent draftsman could

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[15] See, *Dolbear v. American Bell Tel. Co.*, 126 U.S. 1, 535 (1888); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876); *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245, 257 (1928); *Diehr*, 450 U.S. at 187.

> attach some form of post-solution activity to almost any mathematical formula; the Pythagorean theorem would not have been patentable, or partially patentable, because a patent application contained a final step indicating that the formula, when solved, could be usefully applied to existing techniques.

Id. (emphasis added). *Diehr* confirmed this critical holding. 450 U.S. at 192 & n.14.

Moreover, the Court in *Flook* made clear that unpatentable phenomenon of nature must be considered part of the public domain for purposes of considering both the status of the claimed invention as patentable subject matter and its novelty (or obviousness). 437 U.S. at 591-92 (citing *Benson*, 409 U.S. at 67). Significantly, the Court explicitly referenced § 101 in this context. *See id.* at 594 ("Respondent's process is unpatentable under § 101" because once the algorithm was considered part of the prior art there was "no patentable invention") (emphasis added). The Court in *Diehr* again confirmed these holdings, adding only that the old elements of the claim may not be ignored when evaluating patentable subject matter under § 101. *See* 450 U.S. at 188, 189 & n.12. Thus, courts must consider the claim "as a whole" when evaluating patentable subject matter. *Id.* at 188.

This reasoning similarly applies to processes claiming conventional or obvious pre-solution activity, such as taking initial measurements. Such measurements are required as input values to predict the operation of natural laws or to establish the results of employing a mathematical formula. Taking the measurement and predicting or calculating the result remains the performance of a natural law or a mathematical formula.

C. Claim 13 Improperly Claims The Mental Process of Recognizing a Phenomenon of Nature.

In the present case, Claim 13 of the '658 patent purports to possess the mental process of recognizing a medical phenomenon of nature. As discussed above, this patent claims recognition of the statistical correlation for any particular elevated homocysteine level after performing (or ordering or reading the results of) any prior art total homocysteine assay. Allowing the patenting of such claims contradicts this Court's precedent prohibiting patenting of scientific knowledge. Even the most limited construction of this claim involves the mental process of determining that the statistical correlation is likely to be true (*i.e.*, that a scientific fact exists) for a particular individual. This claim is thus nothing like the process of curing of synthetic rubber in *Diehr*, where the results of the mathematical algorithm had direct physical application.

There is no patentable invention in Claim 13 under § 101, in the sense intended in *Flook* and *Diehr*.[16] This claim to the unpatentable mental step of recognizing the unpatentable natural phenomenon of a statistical correlation of homocysteine with cobalamin or folate deficiency did not become patentable subject matter simply by adding the prior art assaying step to

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[16] Claim 13 also lacks sufficient inventiveness to be patentable under § 103. Knowledge of the correlation inherently suggests combination with the prior art assaying step, and thus the process is obvious. *See, e.g.*, *Teleflex, Inc. v. KSR Intern. Co.*, 119 Fed. Appx. 282, 285 (Fed. Cir.2005) (obviousness requires "suggestion, teaching, or motivation" to combine), *petition for cert. pending*, No. 04-1350. Unlike *in Dann v. Johnston*, 425 U.S. 219, 223 (1976), the Court should rule here on the § 101 grounds it certified.

the imputed prior art mental step of correlating.[17] The claimed invention remains a mental process of recognizing a natural phenomenon. Claim 13 merely limits the application of the natural phenomenon to the "particular technological environment" of an assayed fluid, which is not enough for patentability. *Diehr*, at 191.

Moreover, allowing Claim 13 to be considered patentable based on insignificant prior physical activity, *e.g.*, measurement, will lead to unreasonable results. Claim 13, and similar claims to mentally recognizing newly discovered phenomena of nature, would prohibit or chill all such measurements. With such claims patentable, the first person to have discovered that the position of the sun relative to the earth can be used to measure the time of day could have prevented people from looking at the sun. If Claim 13 is upheld, the Court will open the floodgates to such unreasonable patents, burdening science, medicine, and countless everyday activities.

D. Congress Has Not Authorized Patents for Mental Processes of Recognizing Phenomena of Nature.

When enacting 35 U.S.C. § 101 and the corresponding definition of a process in 35 U.S.C. § 100, Congress intended only to codify the existing law of patentable subject matter as the prior statute had been interpreted by this Court. Congress changed the archaic term "art" to "process," defined "process" to include "method," and clarified that a new use of a known

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[17] *Cf.* Brf. for Pet., *Dann v. Johnston*, No. 74-1033, at 34 (Solicitor General arguing no change occurred in physical identity of a computer by mentally associating a new meaning with a physical state of the computer: "[n]or does a ... computer [thereby] become a 'different machine.'")

process or of a known apparatus or composition of matter was patentable. S. Rep. No. 82-1979, at 1, 4, 6 (1952).

However, by codifying pre-existing case law, Congress clearly did not intend to extend patentable subject matter to categories of inventions previously held unpatentable.[18] The House manager for the new Act stated:

> A definition of invention in terms of discovery was included to show that this bill does not distinguish between the word 'invention' and the word 'discovery." The Department of Justice felt that this might open the door to a new era of patents and permit the creation of monopolies in some of the fundamental discoveries in the field of science. I can assure you that was not our intention. We merely intended to state the present law and remove any doubt on this subject.

98 Cong. Rec. A415 (1952) (Extension of Remarks, Hon. Joseph R. Bryson). Congress also rejected a provision that would have permitted the patenting of "a noninventive application of a newly-discovered natural principle." Brief for the Pet., *Dann v. Johnston*, No. 74-1033, at 24 n.21 (citing H.R. 9133, § 101, 81st Cong., 2d Sess. (1950)).

The contemporaneous understanding of § 101 suggests that the Patent Act preserved the prior case law on patentable subject matter, including its limitations regarding scientific

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[18] *See, e.g., In re Schraeder*, 22 F.3d 290, 295 & n.11 (Fed. Cir. 1994); *In re Tarczy-Hornoch*, 397 F.2d 856, 869 (C.C.P.A. 1968) (en banc) (Kirkpatrick, J., dissenting). *Cf. In re Alappat*, 33 F.3d 1526, 1553 n.13 (Fed. Cir. 1994) (en banc) (Archer, C.J., concurring in part and dissenting in part) ("It is erroneous ... to characterize ... nonstatutory subject matter such as a mathematical algorithm as an 'exception' to § 101.")

knowledge. *See, e.g.*, Karl B. Lutz, *The New 1952 Patent Statute*, 35 J. Pat. Off. Soc'y 155, 157 (1953) ("inventions relate to the 'useful arts' (in modern language 'practical arts') but do not 'push back the frontiers of science.'"). Following the 1952 Patent Act, this Court and various Courts of Appeals continued to hold that the previously identified categories of scientific knowledge and mental processes were unpatentable. *See, e.g., Diehr*, 450 U.S. at 185; *Tarczy-Hornoch*, 397 F.2d at 857-869 (citing cases); *Schraeder*, 22 F.3d at 295 (citing cases).

Furthermore, when enacting § 101 in 1952, Congress did not bar this Court from applying its past patentability precedents to new technologies. For example, in 1980, the Court decided that genetically-modified organisms constitute patentable subject matter. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). But contrary to the Court's dicta, that result was not appropriately premised upon a presumed Congressional intent, in codifying § 101, for "'anything under the sun made by man'" to comprise "statutory subject matter." *Id.* at 309 (quoting S. Rep. No. 82-1979, at 5). *See, e.g.*, Malla Pollack, *Originalism, J.E.M., and the Food Supply, or Will the Real Decision Maker Please Stand Up?*, 19 J. Envtl. L. & Litig. 495, 508-09 (2004) (the purpose of the quoted legislative history was to limit not extend patentability).[19] That result was appropriate because Congress intended to preserve the Court's historic interpretive discretion.

For the legal and policy reasons previously stated, this Court should not now extend patentable subject matter to a

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[19] Even if Congress had intended such a broad change to patentability standards, that intent would have been limited to the other three classes of subject matter — machines, articles of manufacture, and compositions of matter — and would not have reflected any change to the standards for processes. A process is not "made by man" and is not any "thing."

mental process of recognizing a natural medical phenomenon. In so holding, this Court will not invalidate broad classes of patents for genetic and biotechnological materials, software, and business methods that resulted from unwarranted extensions of patentable subject matter by the lower courts and consequently by the U.S. Patent and Trademark Office. *See, e.g., State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F.3d 1368 (Fed. Cir. 1998); *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352 (Fed. Cir. 1999); U.S. Patent and Trademark Office, *Interim Guidelines for Examination of Patent Applications* for Patent Subject Matter Eligibility, 1300 O.G. 142 (Nov. 22, 2005). Congress has impliedly ratified most of these specific judicial expansions of patentable subject matter. *See, e.g.*, 35 U.S.C. § 103(b) (biotechnological processes); 35 U.S.C. § 273 (business methods). Reversing the decision here would also broadly invalidate lower court and agency interpretations and would constitute a regulatory taking or would interfere with important sectors of the American economy is unwarranted.

Rather, the Court should acknowledge that Congress has not encouraged further dramatic extensions of patentable subject matter, and should not unilaterally take that step. *See, e.g., Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972) (the Court "should not expand patent rights by overruling or modifying ... prior cases construing the patent statutes.... [without] a clear and certain signal from Congress")

CONCLUSION

In order to best promote progress, protect public health, and prevent unwarranted liability, this Court should invalidate Claim 13 and clarify indirect liability standards.

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